# 510(k) SUMMARY: RISE™ Spacer

**Company:** Globus Medical Inc.
2560 General Armistead Avenue.
Audubon, PA 19403
(610) 930-1800

**Contact:** Kelly J. Baker, Ph.D.
Vice President, Regulatory and Clinical Affairs

**Date Prepared:** November 18, 2011

**Device Name:** RISE™ Spacer

**Classification:** Per 21 CFR as follows:
§888.3080 Intervertebral Body Fusion device.
Product Code: MAX
Regulatory Class: II, Panel Code: 87

**Predicate(s):** Globus Medical CALIBER™ Spacer (K102293)
SE date: January 5, 2011

**Purpose:**
The purpose of this submission is to request clearance for RISE™ Spacers, which have an all titanium design, a smaller overall implant profile, and a modified expansion mechanism, compared to the predicate titanium/PEEK CALIBER device.

**Device Description:**
RISE™ Spacers are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. RISE™ Spacers are provided in different shapes to accommodate various surgical approaches to the lumbar spine (posterior, transforaminal [posterolateral] or lateral) and can expand to the desired height. The implants are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. This device is to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

RISE™ Spacers are manufactured from titanium alloy, as specified in ASTM F136 and F1295. An internal component is manufactured from radiolucent PEEK polymer, as specified in ASTM F2026.

**Indications for Use:**
RISE™ Spacers are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the

lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

RISE™ Spacers are to be filled with autogenous bone graft material. This device is intended to be used with supplemental fixation, such as the REVERE® or REVOLVE™ Stabilization Systems.

**Performance Data:**
Mechanical testing (static and dynamic compression, static and dynamic compression-shear and subsidence) was conducted to demonstrate substantial equivalence to the predicate device.

**Basis for Substantial Equivalence:**
The RISE™ Spacer has been found to be substantially equivalent to the predicate with respect to technical characteristics, performance, design, materials, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 26 2012

Globus Medical, Inc.
% Kelly J. Baker, Ph.D.
Vice President, Regulatory and
Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K113447
Trade/Device Name: RISE™ Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 29, 2011
Received: December 30, 2011

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin C. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number: K113447

Device Name: RISE™ Spacer

**Indications:**

RISE™ Spacers are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

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Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113447